

Advisory Board on Radiation and Worker Health (ABRWH) Dose Reconstruction Workgroup

Teleconference Call: May 29, 2002, 9:00 - 10:30 a.m. Eastern Time

Present: Mark Griffon, Chair; Roy DeHart, Richard Espinosa, Robert (Bob) Presley, Genevieve (Gen) Roessler, Jim Neton (NIOSH)

Draft Minutes

Mark called the teleconference call to order and asked for members to take minutes and submit them to him. He will compile a set, circulate them to the Workgroup, and then distribute them to the ABRWH prior to the next meeting in Denver, July 1 - 2.

Discussion Points presented by Mark via May 23 email

Discussion Points for Conference Call

Charge:

Develop an initial draft of options for a process through which the Advisory Board on Radiation and Worker Health can meet its obligation to review the scientific validity and quality of the National Institute for Occupational Safety and Health's (NIOSH) dose estimation and dose reconstruction efforts; report back to the full Board at the next meeting; and keep the Board apprized as the workgroup proceeds.

Discussion Points:

1. Models of how the Board should conduct the review
 - a. Discuss other models for conducting "peer review" or "independent review"
 - b. Use of "independent" experts or team of experts to perform part of the review for the Board
2. Selection of cases for review
3. Quality of the data used for the assessment
 - a. Access to data
4. Thoroughness of validation and verification performed by the contractor
5. Applicability of models and model assumptions
6. Review (blind or otherwise) of numerical dose estimates
7. Must review to determine if the contractor made a 'reasonable estimate'
 - a. Defined by HHS in the preamble (pg 53-54) as 'estimates calculated using a substantial basis of fact and the application of science-based, logical assumptions to supplement or interpret the factual basis'.
8. Potential Conflict of Interest

Working Group Discussion -- Topics listed above were discussed during the conference call – not necessarily in the order listed above.

1) Models of how the Board should conduct the review

Bob: Does the Board do the dose reconstruction review or do we pick independent reviewers?

Mark: We may need external experts to assist the Board in the process.

Roy - Asked if the contract had been awarded and if the contractor for completing the dose reconstruction's had been announced?

Jim: The dosimetry (dose reconstruction) subcontract has not been awarded yet. Expect it in mid-July or early August.

Roy: Is there a Quality Assurance part in the contract? Are there any guidelines that can be followed from the VA study? How was it done? Was there an independent review?

Jim: Jim Neton indicated that the GAO had recently conducted a review of the VA program that concluded that there was insufficient independent review. He will provide a copy of this report to the working group. He said that as a result of the GAO report a National Academy of Sciences panel chaired by John Till is reviewing the VA program. Jim also indicated he would provide a copy of the contract for the workgroup to review.

Conclusion – Group agreed that most likely there will be a need to hire independent expertise to in some way work with the Advisory Board in reviewing cases.

Gen: This is the Board's (and our) ultimate responsibility. What is the overall picture? Is this a multiyear project? Is there any guidance on what funding is available?

Bob: If we have one or more review committees, at least one person from the Advisory Board should sit on each Review Committee. Who would set the number of committee members to be hired, versus the number of cases.

Jim: One option is to establish a review board composed of ABRWH representatives that work with contractor and report the results of their activities back to the board.

2) Selection of cases for review

Bob: Could some cases be controversial? Would we review them?

Jim: The final decision on the cases resides with the Dept. of Labor. The Board needs to ask if the final rule was followed.

Rich: Some cases are being delayed because the special exposure cohort is not yet set.

Mark: How should cases to review be selected? Random? Based on certain parameters such as geographical, type of exposures, complexity of cases, etc.

Bob: We should look at the total number of cases at each site. Looking at the sites with the majority of claims. Then come up with a percentage of claims to check on a site by site basis.

Jim: Jim Neton suggested that it might be informative for the board to select a distribution of claims based on the level of complexity of the dose reconstruction. Using this approach there would be three classes of dose reconstructions: 1) those where the efficiency process was applied to yield a worst case upper estimate of the dose; 2) those where only a portion of the dose was reconstructed because the dose was believed to be sufficient for compensation; and, 3) those where complete dose reconstructions were performed.

Rich: Is there or should there be a priority list?

Roy: We need an Excel Spread Sheet for the parameters. At any site there are many things to consider: exposure – internal or external, the diagnosis (the type of cancer may differ from the normal population), the duration of employment.

6) Blind or otherwise

Gen: Should it be blind or otherwise?

Jim: It should be a blind independent review. However, in many cases one will not need to be determined on accuracy but on the likelihood since NIOSH is conducting dose reconstruction only for use in determining probability of causation. Need to know that it is likely that the overwhelming majority of cases will be denied. Will it be a completely blind review? Do we start with the claimant or with the contractor?

Jim: NIOSH will provide us with the contractor's scope of work. That will tell us more about what NIOSH plans to do.

3) Quality of Data and 4) Validation and Verification

Mark – Discussed the possibility of giving the Advisory Board or Review Committee the raw data and letting the committee make their own decisions. Discussed the quality of data used in the assessment and will the Review Committee have all the needed data to make a good decision. Do we know, or think, that NIOSH had all the data they needed to make a correct decision. There may be mistrust if contractor is basing their estimates solely on personal dose records provided by DOE. Whoever conducts the review must consider whether NIOSH and their contractor had the needed data to do an adequate job?

Roy - Discussed making sure that we the Advisory Board or Review Committee, have adequate time to review the raw data. We need to come up with our own protocol for handling the data.

Gen: We should not commit to more than we can do. We need to define the scope of the review. We should not propose more than the funding will allow. Where do we go for funding information or is that not our responsibility?

Mark: The Board or the review team should try to assure that all data has been reviewed. We also need to evaluate the Conflict of Interest issues. NIOSHs subcontractor is required to have a conflict of interest plan, the Boards review should consider whether they adhered to the plan.

Roy: What kind of numbers (claimants) are we looking at?

Jim: There are 4,500 in house now. There will be 10,000 to 12,000 eventually. The contractor is bidding to do 8,000 claims in the first year. It is Jim's opinion that the program may go on for a decade or so. Work may start at the beginning of 2003. We will get a status report at the next meeting. With regard to the quality of data, NIOSH is informing the claimants as to what was used. Our question will be: Did NIOSH do an adequate job? Did NIOSH adequately address the claimants?

Mark: Spoke of his experience at Paducah. From that he says we need to determine if NIOSH and DOE made the best possible effort in obtaining all the data. However, it will be more difficult to audit DOE.

Mark: We merged discussion topics 3) and 4) on the list of discussion points. We can assume that the Board will do 5) (Review of Models and Model assumptions). Let's discuss 7).

7) Must review to determine if contractor made a 'reasonable estimate.'

Mark: Talked about language from the statute and how NIOSH defined 'reasonable estimate' in the dose reconstruction preamble (page 53-54). The review team needs to look at this. The Board also needs to review the Conflict of Interest. We want the claimant to be reassured there are no conflicts of interest at any levels – NIOSH, contractor, Advisory Board, and the independent reviewers.

Bob: Discussed the fact that every person on the Advisory Board should be allowed input and then the Advisory Board should make the final decision.

Rich: There needs to be someone independent of DOE or there will be no credibility.

Mark: There will be a lot of rejected claims and a lot of angry claimants. This is an issue we need to identify to the whole Board – auditing of DOE.

Roy: If the Board is to have an influence at all with Conflict of Interest it first needs to review the contract (with the subcontractor?).

Jim: What has merit is reviewing the dose reconstruction process rather than reviewing the contract itself. It is likely that there will be one contractor but there may also be a database management subcontractor.

Mark: Maybe the review should make sure that the contractor complies with the Conflict of Interest plan.

Roy: There will be conflict of interest issues no matter who gets the contract.

Mark: While we know whoever gets the contract will have conflict of interest issues we need to make sure there is more transparency with regard to the claimants.

Mark: We should wrap things up for now. Jim will send a copy of the contract to all of us prior to our next conference call. Does anyone have any final thoughts.

Jim: Will send out the technical part of the contract. We should reflect on it.

Roy: We need to lay out the agenda items. We need to realize the magnitude of what we're doing. We need to have specific questions for the Board to cover.

Bob: Stated that he had seven items that he thought should be addressed by the Working Group and incorporated into the review process or ground rules for the review:

1. Define the location for the review
2. Define the number of persons on a review committee.
3. Set standard or key questions to be asked at the review.
4. Ask for claimant input, if possible.
5. Report the finding of the review committee to the claimant in a timely matter.
6. Send a copy of the findings to DOE/DOL and Claimant?
7. Report findings to the Advisory Board.

Mark: We need to define the process including the level of the commitment.

Gen: We need to present to the Board the overall structure, we need to come up with a timeline, and determine what our time commitment is.

Mark: We should all look at the seven points, and think more about the case load and the time commitments for the review process.

Gen: Perhaps the approach is to present what we think is an adequate review and not be required to think about the money.

Mark: Let's set up the next conference call. We should do before our next Board meeting.

Next Conference Call: Monday, June 24, 9 a.m. Eastern time

Workgroup should get teleconference notes to Mark by June 4. He will distribute to the workgroup by June 6. Jim will send his materials to workgroup by Fed Ex.